

## **REMARKS/ARGUMENTS**

Claims 1-5, 8-18, 20, 22, 23, 25, 26, 28 and 29 have been allowed. Claim 30 has been cancelled by way of this amendment without prejudice or disclaimer. Claims 19, 21, 24 and 27 have been amended by way of this amendment. Claims 1-5 and 8-29 remain pending in this application upon entry of these amendments.

### **Telephonic Interview on March 23, 2004**

At the outset, Applicants wish to thank Examiners Manjunath N. Rao and Rebecca Prouty for the courtesies extended to Applicants' representatives Adda C. Gogoris and Heather Morehouse Ettinger during the telephonic interview on March 23, 2004. Applicants also wish to thank Examiners Rao and Prouty for informal telephone conversations on March 24 and 25, 2004.

During the interview, the outstanding claim rejections of claims 19, 21, 25 and 27 were discussed. With regard to claims 19 and 27, agreement was reached that deletion of the word "human" in part (ii) of each of these claims would obviate the § 112, second paragraph rejection. The Examiners also indicated that the §112, second paragraph rejection of claims 21 and 24 because of the term "region" would be withdrawn without further amendment. (Some instances of the word "region" were subsequently deleted at Applicants' initiative only because there was no longer antecedent basis for the word "region" in the body of the claims. No narrowing of claim scope was intended.) With respect to claim 30, it was agreed that the claim would be cancelled, without prejudice or disclaimer.

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The Examiner has rejected claims 21 and 24 for being indefinite because of the phrase “in a region of the human C2/4GnT gene.” In particular, the Examiner objected to the term “region.” However, by way of the telephonic interview held on March 23, 2004, the Examiner agreed to withdraw these rejections without further amendment of the claims. Accordingly, Applicants respectfully request formal withdrawal of these rejections.

Claims 21 and 24 have also been rejected by the Examiner as indefinite because the phrase “amplifying by PCR a segment of patient’s DNA comprising a region that is at least 95% identical to a subsequence of . . .” is allegedly unclear. Specifically, the Examiner alleges that it is unclear how one can conclude that the patient’s sample DNA is 95% identical to a subsequence of SEQ ID NO:1 even before amplifying the same.

Without conceding the Examiner’s position, claims 21 and 24 have been amended to delete the phrase “at least 95% identical to a subsequence.” In addition, during the March 23, 2003 interview, the Examiners also suggested to Applicants to amend the claims to recite that a segment of the patient’s DNA would be amplified using primers that are capable of amplifying one of the three specified subsequences of SEQ ID NO: 1 or a fragment of these subsequences. As suggested by the Examiners, claims 21 and 24 have been amended to recite amplifying the DNA “using amplification primers capable of amplifying a subsequence of SEQ ID NO: 1.” Accordingly, withdrawal of these rejections is respectfully requested.

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**Rejections Under 35 U.S.C. § 112, First Paragraph –  
Written Description Requirement**


Claim 30 has been rejected for alleged failure to fulfill the written description requirement.

Without conceding the Examiner's position, claim 30 has been cancelled, without prejudice or disclaimer. Accordingly, this rejection is moot.

**Rejections under 35 § 112, first Paragraph - Enablement**

Claims 21 and 24 have been rejected for failure to fulfill the enablement requirement. Applicants note that the language of this rejection indicates that the Examiner made this rejection based on the language of these claims prior to the previously submitted Amendment (mailed October 3, 2003). Consequently, Applicants' representative Heather Morehouse Ettinger called the Examiner on January 12, 2004 to discuss these rejections. Examiner Rao acknowledged that the enablement rejection should be applied to the language "at least 95 % identical to a subsequence of SEQ ID NO: 1" and also be maintained because the specification allegedly did not provide the entire genomic sequence of the C2/4GnT gene.

Without conceding the Examiner's position, the phrase "at least 95 % identical to a subsequence of SEQ ID NO: 1" has been deleted from claims 21 and 24. In addition, as pointed out during the March 23, 2004 telephonic interview the nucleotide sequences recited in the claims are genomic sequences that occur uninterrupted in the human genome. Support for this position can be found, for example, in the following passage of the specification (page 22, line 25 - page 20, line 2):

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## Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

Dated: April 2, 2004

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Appl. No. 09/874,390  
Reply to Office Action of January 5, 2004